architecture using (a) nucleic acid molecule(s) or regulatory sequence(s) that result in increased de novo expression of at least two cell cycle interacting proteins, wherein one of said cell cycle interacting proteins is an E2F protein, and to a composition.

REMARKS

Claims 1-41 are present in this application and have been subjected to restriction by the Examiner under 35 U.S.C. §121 (37 C.F.R. §1.142) as set forth on pages 2-5 of the December 30, 2003 communication from the U.S. PTO. In support of the present restriction requirement, the Examiner has alleged that the subject matter defined by the claims of the present invention represents distinct inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1. In support of the present restriction requirement, the Examiner alleges that the subject matter defined by the claims represents distinct inventions stating that "the inventions listed as Groups I-XV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features."

As indicated, and in order to be fully responsive to the Examiner's requirement for restriction, Applicants provisionally elect to prosecute the subject mater of Group XII, claims 1-2, 13-14 and 31, drawn to a method for modifying plant growth and/or yield or modifying architecture using (a) nucleic acid molecule(s) or regulatory sequence(s) that result in increased de novo expression of at least two cell cycle interacting proteins, wherein one of said cell cycle interacting proteins is an E2F protein, and to a composition. Applicants reserve the right to file one or more divisional applications directed to the non-elected subject matter in this application.

Pursuant to 37 C.F. R. § 1.111 and § 1.143, Applicant hereby traverses the Examiner's requirement for restriction for the following reasons.

An Examiner's authority to require restriction is defined and limited by statute:

> If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions.

35 U.S.C. 121, first sentence (emphasis added).

The rules which the PTO follows in implementing unity of invention considerations in PCT applications are found in 37 C.F.R.§ § 1.475-1.477, 1.499, and MPEP § 1893.03(d). Whether an application is at the international or national stage, PCT Rule 13 governs a unity of invention analysis. When making a lack of unity of invention requirement, the Examiner must (1) list the different groups of claims and (2) explain why each group lacks unity with each other group i.e., why there is no single general inventive concept specifically describing the unique special technical feature in each group.

Under PCT Rule 13, a group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression "technical feature" is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art.

Notwithstanding the Examiner's characterization of the present invention, Applicant respectfully submits that there is one single general inventive concept which specifically describes the unique special technical feature of each group. This singe, general inventive concept involves the co-expression of at least two genes coding for cell cycle interacting proteins that form a complex useful in a method for modifying plant growth and/or yield and/or

architecture. This phenomenon is neither disclosed nor suggested in the prior art. Thus, Applicants assert that there is a technical relationship among the groups of claims involving one or more of the same or corresponding special technical features. As such, the restriction requirement is improper and should be withdrawn.

Applicants respectfully submit that non-unity objections were not raised in the International Preliminary Examination Report (IPER) to PCT/EP00/02441, which PCT application corresponds to the above-identified section 371 application. A copy of the IPER was submitted to the U.S. PTO upon filing the present application In other words, the PCT application complied with the above-mentioned PCT rules. Nevertheless the Examiner cites the same PCT rules to allege non-unity.

The Examiner's position is that the technical feature linking the inventions of Groups I-XV appears to be the use of a nucleic acid molecule or regulatory sequence to modify plant growth and/or yield or modify architecture, wherein the introduction into a plant of the molecule(s) or regulatory sequences(s) results in increased or de novo expression of at least two cell cycle interacting proteins capable of forming a heterodimeric complex. According to the Examiner, this technical feature is obvious or anticipated over U.S. Patent No. 5,514,571, in view of Hemerly et al. (1995) The EMBO J. 14(16):3925-3936 and Riou-Khamlichi et al. (1999) Science 283:1541-1544, and "therefore does not constitute a special technical feature as defined by PCT Rule 13.2, because it does not define a contribution over the prior art." December 30, 2003 Restriction Requirement, page 7.

Applicants respectfully submit that US Patent No. 5,514,571 describes the use of Cyclin D1 as a negative regulator of cell proliferation. The paragraph in this document cited by the Examiner describes fibroblasts being micro-injected with constructs encoding $p33^{cdk2}$, cyclins A,

D1 and E, either alone or in paired combinations. The aim was to study effects on cell morphology. The authors observed an increase of kinase activity when cdk2 was combined with CycA or CycE, and the opposite was observed for cdk2 with CycD1. Applicants respectfully submit that U.S. Patent No. 5,514,571 is from a non-analogous art. The experiments described in the '571 patent were performed in an animal system, with single cells in order to study effects on cell morphology. This is in contrast to the unifying concept of the invention which is to modify plant growth and/or yield and/or architecture by co-expressing at least two genes coding for cell cycle interacting proteins that form a complex.

Applicants further submit that an animal body is fundamentally different from plants. Since plants possess meristems, consequently the role of cell cycling is different between plants and animals. Whereas continuous cell division is a prerequisite for normal plant development, cell proliferation in animals is usually linked to a malignant situation such as cancer. This link is also made for US Patent No. 5,514,571. Column 4, lines 11-28, describe that one of the aspects of the invention is to provide a method of detecting a state of quiescence, hyperplasticity or neoplasia in a biological sample. Thus, one skilled in the art would not direct himself to documents describing effects of cell cycle proteins on mammalian fibroblast cell morphology in relation to cancer such as the '571 patent, for solving a problem of modifying plant growth and/or yield or modifying architecture. In addition, it is an object of the present invention to modify the architecture and/or the yield of a plant. This implies changes on the level of the whole organism, or at least on the level of an organ, which contrasts to the scope of US 5,514,571 wherein proliferation of cells in *in vitro* cultures is envisaged.

Hemerly et al. is another document cited by the Examiner as lack of a unifying inventive concept. The document discloses transgenes with modified cdc2 kinase expression or activity.

Wild type cdc2a is overexpressed ($cdc2a^+$) and also mutant forms thereof (T14A/Y15F; D147N (with extra mutation T223A; abbreviated as N147A223)). Both *Arabidopsis* and tobacco were used for transformation. Two tobacco lines of the N147A223 mutant were further studied: DN5 and DN9. Crosses of the various constructs were made, among which $cdc2a^+$ x DN5 and $cdc2a^+$ x DN9: these crosses show again a normal phenotype.

In contrast to the unifying concept linking the groups of the invention identified by the Examiner, in this work only a single gene is studied. On p.3925 of this document , in the right column, lines 32-36, it is stated "the construction of dominant mutations in **a** plant Cdk and **its** subsequent overexpression in plants in an attempt to deregulate the normal function of the wild-type gene." It is thus the aim to disturb the normal cdc2a function and the crosses (with two forms of the same gene) were used to reveal the role or mechanism of action of the introduced mutations. There is no suggestion whatsoever for combining two different genes, let alone two different genes that form heteromeric complexes. The strategy used in the present invention is therefore very different from the strategy described in Hemerly et al.

The Examiner has also cited Riou-Khamlichi et al., which describes transgenic *Arabidopsis thaliana* plants with a 35S::CycD3 construct. Because no shoot regeneration could be obtained with a normal 35S::CycD3 construct, another strategy was used in which plants were transformed with 35S::recomb. site::GUS::recomb. site::CycD3. These transformants were crossed with a transgenic plant carrying a hsp::FLP recombinase, resulting in viable 35S::CycD3 transgenic progeny. No formation of a heteromeric protein complex is suggested, much less the use of two cell cycle interacting proteins. Furthermore, this document was not considered particularly relevant in the International Search Report (A-citation).

In the present patent application, the technical underlying problem is stated as "to provide

means and methods for enhancement of plant growth, and/or yield and/or modified architecture in particular in the entire plant, or specific parts of said plant, which are particularly useful in agriculture" (page 6, lines 15-18). None of the cited documents relate to the problem that is solved in this patent application. Further, none of the three documents, taken separately or in combination, suggest generating plants or plant parts that are useful in agriculture by using combined expression of two cell cycle interacting genes, whereby the two cell cycle interacting proteins form a complex with a function that is different from the two separate proteins alone. It is respectfully submitted therefore, that the use of at least two cell cycle interacting proteins for modifying plant growth and/or yield and/or plant architecture does constitute a single general inventive concept and therefore request that the restriction and/or election requirement be withdrawn.

The courts have recognized that it is in the public interest to permit applicants to claim several aspects of their invention together in one application, as the Applicant has done herein. The CCPA has observed:

> We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. § 112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved.

In re Kuehl, 456 F.2d 658, 666, 117 U.S.P.Q. 250, 256 (CCPA 1973).

This interest is consistent with the practical reality that a sufficiently detailed disclosure supporting claims to one aspect of an invention customarily is sufficient to support claims in the same application to other aspects of the invention.

Applicants respectfully submit that in view of the continued increase of official fees and the potential limitation of an applicant's financial resources, a practice which arbitrarily imposes

restriction requirements may become prohibitive and thereby contravene the constitutional purpose to promote and encourage the progress of science and the useful arts. Moreover, under the regulatory changes as a consequence of the General Agreement on Trade and Tariffs (GATT), Applicant is required to conduct simultaneous prosecution, as here, requiring excessive filing costs or a compromise of the term of their patent assets.

It is vital to all applicants that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications which are filed to prosecute claims that the Examiner held to be independent and distinct can be vulnerable to legal challenges alleging double patenting. The third sentence of 35 U.S.C. § 121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional application or a patent issued thereon, does not provide comfort to applicants against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that § 121 protects a patentee from an allegation of same-invention double patenting, *Studiengesellschaft Kohle mbH v. Northern Petrochemical Co.,* 784 F.2d 351, 355, 228, U.S.P.Q. 837, 840 (Fed. Cir. 1986). *In Gerber Garment Technology Inc. v. Lectra Systems Inc.,* 916 F.2d 683, 16 U.S.P.Q. 2d 436 (Fed. Cir. 1990), that court held that § 121 does not insulate a patentee from an allegation of "obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on the divisional application.

All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which an applicant's legitimate patent rights are

exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public's interest in the legitimacy of issued patents, Applicants respectfully urge the Examiner not to require restriction in cases such as the present application wherein various aspects of a unitary invention are claimed.

Hence, it is again respectfully urged that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims.

Respectfully submitted,

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